



April 7, 1997

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

4/15/97

0110 '97 SEP 19 P1:39

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is PMS Formula. The dietary ingredients that are the subject of the statement are Magnesium, Vitamins B6, B12 and Folic Acid. The statement of nutritional support reads as follows:

" A woman's formula for the early reproductive years. Magnesium (aids in muscle relaxation) and Vitamins B-6, B-12 and Folic acid provide added nutrition to improve nervous response and help rebuild healthy tissue following menses."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory Counsel

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